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DEVELOPMENT OF A HIGH DENSITY PERCUTANEOUS CONNECTOR SYSTEM

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Abstract

This report summarizes activity over the period from July15, 1998 through October 15, 1998 on NIH Contract N01-DC-7-2103, "Development of a High Density Percutaneous Connector System". Implants at HMRI for electrostimulation and with grooved Titanium, beaded Titanium and Laminin-5 to aid skin attachment are in progress. Work continues on osseointegration and the implanted ribbon cable. In general, osseointegration is satisfactory, skin attachment is improving and two of four cables look good; the other two cables show excessive leakage. All cables have wire breakage. The excessive leakage and breakage are under investigation. An 81-pin version of the connector is scheduled for implant this year. The Quick Disconnect design is complete, but requires excessive torque for elastomer compression. Lubricants and design modifications are being used to reduce this problem. The last ten dummy connectors for frit studies are at IJR.

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I. Background and Review of Contract Requirements

This report summarizes activity during the specified quarter, on NIH Contract N01-DC-7-2103, "Development of a High Density Percutaneous Connector System". Over the course of this contract, a high density, planar, low profile connector system is being developed that incorporates pad grid array technology. This technology has unique advantages as applied to a percutaneous interconnect system. In particular the connector system will be low in profile, easy to clean, sealed against ingress of contaminants, offer low mechanical resistance to mating and demating and provide a very high number of contacts in a small diameter. The connector system will be implanted in a suitable animal model and the appropriate electrical, mechanical, and biocompatible properties of the system will be assessed. The specific technical requirements of this connector system as detailed in the contract are explained below:

- The connector will incorporate a pedestal that can be attached to the skull in a mechanically stable manner. The pedestal will be designed to accept a replaceable connector assembly. All materials of the pedestal in contact with tissue will be biocompatible and the profile of the pedestal will be low enough to minimize any physical trauma during mating and demating of the connector or due to normal physical activities.

- The connector assembly will be high-density with at least 70 contacts. The electrical isolation between the contacts or between the contacts and the body should withstand at least 18 volts without breakdown. The connector contacts when mated should be capable of passing up to 20 mA of current with less than a 1.0 volt drop across the connection. A simple method of mating and demating the upper and lower surfaces of the connector should be provided. In addition, a convenient means to attach electrical leads to the connector is needed.

- The connector will be designed from materials that are durable and can withstand the physical abuse from normal activities of daily living. The interface between the connector and the skin must be such that the passage of microorganisms into the body and fluid drainage out of the body is prevented.

- In earlier studies connectors had 5 separate loops of insulated wire, each 2 inches long. Because of wire breakage observed during these studies it is necessary to make a more durable and a more realistic part. The present cable is a ribbon one inch long with five 2-mil Pt/Ir wires, coated with Parylene and Silicone. The wires are looped so there are five loops for testing. The 2 mil wires are more rugged and easier to work with for initial tests, but 1 mil wires will be used after the ribbon cable concept is developed. An 18 Volt bias will be maintained on the wires relative to an implanted platinum wire connected to one of the unused contacts or the Ti connector body. The leakage current of the cable wires will be monitored with a maximum acceptable value of 10 nanoamperes.

- Performance of the connector system will be tested in a suitable animal model. After three to six months of implantation, the connector assembly will be explanted and gross and microscopic examinations will be performed to study the attachment of the pedestal to the skull, the attachment of the skin and soft tissue surrounding the pedestal to the pedestal wall and the reaction of adjacent tissue to the implanted device.

- Finally, design changes and improvements, if needed, will be recommended. A set of connectors will be fabricated and sent to the NIH for implantation. Initial testing will be in cats with final tests conducted in non-human primates.

II. HMRI Work

Three connectors were implanted during this quarter: two with Ti beaded surfaces and one with a grooved-Ti surface coated with Laminin-5. All had implanted ribbon cables for leakage and survivability tests.

All three implants are on the skull midline and show healthy skin. The degree of attachment varies. The Laminin-5 surface seems not to have attachment to the Ti surface.

Two of the three cables are showing excessive leakage of several hundred nA (the acceptable limit is 10 nA and the new cable design was reported in the last QPR). Since an earlier cable of similar construction and one current implant are well under the leakage limit, the excess leakage is not yet considered a design problem, but a matter of technique in building and installing the cable. However, this can not be determined with certainty until the cable is explanted and examined. There is also, apparently, some breakage of the wires in the cable. All cables that have been tested show breakage.

III. Status of Fritting Experiment

As reported last quarter there have been problems with apparent shrinkage in the ceramic frit. However, this seems to be improving with experience. In the last QPR it was reported that ten dummy connectors with additional thickness to allow for the shrinkage would be delivered to IJR in August for frit with CABAL-12. Results from these ten are not available yet. It is planned that these will be the last dummy connectors in the frit experiment.

Dr. Yoon's opinion is that the CABAL-12 frit can be made to work on a 64 or 70 pin connector, but not on the 81-pin connector currently being built (or connectors with higher pin counts). Dr. Yoon is President of IJ Research where the fritting work is being done. Because of the pin limit, and, perhaps for reasons of cost and manufacturing control, an alternative to the ceramic frit is required.

IV. Investigation Into Other Pin Matrix Materials

The last QPR reported completion of the hot box for accelerated testing at 80 to 90 °C and work on the initial materials to be tested with tests expected to start in August. Delays in obtaining several materials have slipped start of testing to mid-November. Initial tests to be run are:

- Silicone and Parylene coated one mil Pt/Ir wires with three treatments of the Parylene surface for Silicone adhesion. These wires will be immersed in Ringers Solution for aging. This supports the ribbon cable work.

- A 2x3-inch 200 mil thick slab of Ti with twelve quarter inch diameter holes into which various polymers are placed will be aged in Ringers. One side will be coated with Silicone similar to the construction of the first stage (lower section) of the connector. Two Pt/Ir wires will be imbedded in each material for electrical leakage testing. Two assemblies of this type will be tested, one completely immersed and one with only the bottom side in Ringers. This is to test various possible matrix materials.

- A 0.25 inch thick block of EpoTek 301 2x3 inches with buried wires for leakage tests. This is for comparison to a block of EpoTek, which BioElectric Corporation has had in Ringers Solution for more than three years.

- A first and second stage connector (bottom and top) with Shin Etsu GBM elastomer between the sections compressed as normal. The first stage will have a normal EpoTek 301 matrix and the second stage will have a ceramic core held in place by thin layers of EpoTek 301. The first stage will have two pieces of ceramic imbedded in the EpoTek (these pieces hold the pins in place during fabrication). This assembly will have one side ground flat so it will not roll and it will be placed in Ringers approximately half way up the matrix material.

V. Connection of Top and Bottom Sections with a "Quick Disconnect" Mechanism

The Quick Disconnect design is complete, but its construction is being delayed because of excess torque required to attach the two parts with sufficient anisotropic elastomer compression. The "old" connector design requires tightening two 0-80 screws to 14 ounce-inches of torque. Of the 14 ounce-inches, a little over one ounce-inch supplies the elastomer compression. The other 13 ounce-inches overcome screw thread friction. This has been measured and agrees with engineering handbook information on thread friction. The Quick Disconnect design would require about 75 ounce-inches of torque. This is more than a normal young person can apply with fingers on a knurled half-inch diameter object, certainly more than many patients could apply. Also, it is enough that maintaining good skull contact would certainly be problematic.

Lubricants to reduce screw friction have been tried with only moderate success. A lower compression force elastomer would be more desirable and work continues in that direction.

VI. Reliability of the Anisotropic Material from Shin-Etsu

The first implant of the Shin Etsu GBM material was reported in the last QPR. This material has proved to be an improvement over the older MAS material with regard to reliability. However, one complete failure was observed by myself and Dr. McCreery. The elastomer was replaced and the failed material was returned to BEC and tested. It proved to be approximately 50% functional. Microscopic examination and electrical tests have not shown the failure mechanism.

VII. 81-Pin Connector

The 81-pin connector design reported in the last QPR continues to test well. Two connectors will be implanted at HMRI this year. These parts will have grooved-Ti sides for skin attachment and five-loop ribbon cables.

VII. Skin Growth

The two connectors with Ti beaded surfaces reported in the last QPR have been implanted and are doing well.

Also reported in the last QPR were two connectors to be treated with Laminin-5 for skin attachment. One of these has been implanted. The skin appears healthy, but there is no apparent attachment.

An electrostimulation experiment started in June was lost because of head bumping by the animal. Since the experiment was lost early no histology was performed on the first (lower) section (skin attachment), but the skin looked healthy and osseointegration was 88%. This was the half-electrostimulation experiment (half the dummy connector was stimulated, the other half was not stimulated).

A second electrostimulation was also lost because of head bumping. Skin was healthy at the time of loss, but no histology was possible.

Both electrostimulation experiments were medial implants in which the skin dropped below the first (lower) connector stage to the pedestal. The skin is naturally thinner at the mid-line than to the side where previous implants were made and these cats were small. The position and animal size both contributed to the drop in skin level. In the future larger males will be used to avoid losing the skin experiment. With the exception of this "skin drop" problem, the skin

attachment seems to have been helped by moving to the medial implant, away from the ears and ear motion. The medial implant will continue to be used.

IX. Activities for the Sixth Quarter

During the next quarter:

- Implant five electrostimulation experiments.
- Continue the two connectors with Ti beads to study skin attachment.
- Continue the one connector with Laminin-5 for skin attachment.
- Implant two 81-pin connectors with grooved Ti sides for skin studies.
- Implant two connectors with Laminin-5 for skin studies.
- Implant cables on all connectors except the electrostimulation experiments.
- Continue work on a ceramic frit matrix material in dummy connectors.
- Continue to look for long-term pin matrix polymer.
- Start accelerated life testing.
- Continue work to make the Quick Disconnect design practical.
- Continue testing the 81-pin connector design.